REMARKS

Claims 1-19, 21-23, 45, and 68 were previously pending in this application. By this amendment, Applicants have amended claims 1-3, 23, 45, and 68 to clarify that the agent administered to the subject is hyaluronic acid. Support for the amendment can be found in claim 9 as originally filed. Applicants are canceling claims 9, 10, and 11 without prejudice or disclaimer. Claims 91, 115, 139-141, 143, 145-147, 149, 151-153, 155, 157-159, and 161, which were previously withdrawn due to the restriction election are cancelled herewith without prejudice or disclaimer. As a result claims 1-8, 12-19, 21-23, 45, and 68 are pending for examination with claims 1, 23, 45, and 68 being independent claims. No new matter has been added.

Rejections Under 35 U.S.C. §112, second paragraph

The Examiner has rejected claims 1-19, 21-23, 45, and 68 under 35 U.S.C. §112, second paragraph as unclear. Applicants respectfully traverse the rejection.

The Examiner agreed at page 3 of the Office Action that the specification as filed teaches that a statistically significant reduction in the likelihood of infection may be determined, but the Examiner concludes that the specification does not describe how this determination is made. Applicants respectfully disagree with the Examiner's conclusion and assert that the specification as filed does describe how the determination of reducing the likelihood of infection is made. In addition, Applicants submit that such determinations are routinely performed, and in fact are required, for any clinical trial and the methodology is well known and routinely practiced.

As set forth in the response filed February 4, 2004, page 22, lines 1-11 of the specification as filed describes methods that are routinely used in the therapeutic arts to determine whether or not a compound reduces the likelihood of infection or other disease condition. Such routine methods include a comparison of acquisition of infection by test versus control subjects that have been exposed to streptococcal or staphylococcal bacteria. As with any therapeutic, one of ordinary skill would recognize that a comparison of infection between test and control subjects permits the assessment of the reduction in the likelihood of infection brought about by the administration of the given compound (in this case, hyaluronic acid) to a subject. For example, a test subject or group of test subjects and a control subject or group of control subjects may be exposed to streptococcal or staphylococcal bacteria and hyaluronic acid

administered to the test but not the control group to provide an assessment of the reduction in the likelihood of infection in the test group versus the control group.

Although agreeing that the specification teaches that a statistically significant reduction in the likelihood of infection may be determined, the Examiner suggests that the specification does not indicate the methods one would use to determine the reduction in likelihood of infection. Applicants respectfully point out that methods of determining an infection in a subject are described in the specification. For example, at page 12, lines 25-30, methods of determining infection in a subject are described as "known to those of ordinary skill in the medical arts and include, but are not limited to, swab of affected region for bacterial culture or rapid streptococcal diagnostic testing such as the latex agglutination or enzyme immunoassay of swab specimens". The specification also states at page 12, lines 21-25 that the presence of an infection may be symptomatically determined by observing a subject for symptoms as a determination that the subject has a streptococcal or staphylococcal infection.

The specification as filed clearly teaches that both symptomatic and asymptomatic infections can be identified using routine methods known in the art. Applicants respectfully submit that the methods of determining an infection are set forth in the specification as filed and that these methods in conjunction with standard methods of comparing infection in a test subject versus a control subject (e.g. a test subject treated with hyaluronic acid versus a control subject not treated with hyaluronic acid) would allow one of ordinary skill to determine a reduction in the likelihood of infection. Thus, Applicants respectfully submit that the metes and bounds of "reduce the likelihood" would be understood by one of ordinary skill based on the routine practice in the art and can also be ascertained based on the teaching provided in the specification as filed.

Applicants request the Examiner reconsider and withdraw the rejection of claims 1-19, 21-23, 45, and 68 under 35 U.S.C. §112, second paragraph.

Rejections Under 35 U.S.C. §103(a)

The Examiner rejected claims 1-19, 21-23, 45 and 68 under 35 U.S.C. §103(a) as unpatentable over Schrager et al.

Applicants do not agree that the invention as claimed is obvious in light of the Schrager et al reference. Applicants assert that the teaching of Schrager et al is limited to *in vitro* methods

and does not teach or suggest that the monoclonal antibody to CD44 IM7.8.1 prevents adhesion of bacteria to the CD44 protein and inhibits bacterial colonization of the pharynx.

Although not conceding that the Schrager et al reference renders obvious the claimed invention, in the interest of expediting the allowance of the case, Applicants have amended claims 1-3, 23, 45, and 68 and have cancelled claims 9-11 to reflect that the agent that is administered to the subject is hyaluronic acid.

In light of the amendment to the claims, Applicants request reconsideration and withdrawal of the rejection of claims 1-19, 21-23, 45 and 68 under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicants' representative at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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